



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,814	08/26/98	DOHI	M 051505

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WASHINGTON DC 20037

EXAMINER
BERMAN, A

ART UNIT
1615

PAPER NUMBER

DATE MAILED: 01/21/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,814

Applicant(s)

Dohi et al.

Examiner

Alysia Berman

Group Art Unit

1615

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19-44 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19-23, 26-32, and 38-44 is/are rejected.

☒ Claim(s) 24, 25, 33-37, and 42-44 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of Preliminary Amendment A filed on 26 February 1998 and Preliminary Amendment B filed on 4 December 1998.

Specification

1. The abstract of the disclosure is objected to because it should not be more than one paragraph and is not intended for use in interpreting the claims. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claims 24-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Claims 33-37 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
4. Claims 42-44 are objected to because of the following informalities: the claims recite an average particle size of 10-350 m. It is assumed that this is a typographical error and should be corrected to 10-350 microns. Appropriate correction is required.

Art Unit: 1615

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-23, 26, 28-32, and 38-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suzuki et al. (4613500). Suzuki et al. teach a powdery composition for nasal administration that contains a polypeptide and a water-absorbing and water-insoluble base (abstract), and a water-absorbing and gel-forming base in an amount of 1 to 50 wt. % (col. 5, lines 10-25). The structure of the composition is such that the drug may be dispersed on or in the water-absorbing and water-insoluble base (col. 5, lines 53-65). At least 90 wt. % of the particles of the powdery composition, which may include the drug and both bases, have a diameter of 10-250 microns. Suzuki et al. teach the use of a drug with a molecular weight between 1,000 and 300,000 (col. 2, lines 57-63), such as vasopressins, luteinizing hormone-releasing hormones, insulin, and calcitonin (col. 2, line 64 to col. 3, line 25).

Applicant's claims are to a product, therefore, no weight is given to the process in which the product per se is obtained. The prior art teaches the product of a powdery composition for nasal administration wherein the drug is dispersed on or in the water-absorbing and water-insoluble base and optionally mixed with a water-absorbing and water-soluble base. It would have been obvious to one skilled in the art at the time of the invention to mix the drug with the

Art Unit: 1615

water-absorbing and water-insoluble base in order to have the drug dispersed on or in that base and add a water-absorbing and water-soluble base with the reasonable expectation of obtaining a composition that is efficiently absorbed through the nasal mucosa with a sustained release effect.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 19-23, 26-32, and 38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. as applied to claims 19-22, 26, 28-32 and 38-41 above, and further in view of Makino et al. (5626871). Suzuki et al. teach all of the limitations of the claims as stated above. Suzuki et al. do not teach the use of non-peptide/non-proteinaceous drugs. Makino et al. teach the use of non-peptide/non-proteinaceous drugs, such as steroidal anti-inflammatory drugs and non-steroidal anti-inflammatory drugs (col. 7, line 60-col. 8, line 26) in the form of powdery compositions for nasal administration (col. 4, lines 11-13). It would have been obvious to one skilled in the art at the time of the invention to substitute a non-peptide/non-proteinaceous drug such as described in Makino et al. for a peptide/proteinaceous drug such as described in Suzuki et al. with the reasonable expectation of producing a medicament that is efficiently absorbed through the nasal mucosa.

Art Unit: 1615

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is (703) 308-4638. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234 or 1235.

TK Page
THURMAN A. PAGE
SUPERVISORY PATENT EXAMINER
ART UNIT 152 16-18

Alysia Berman
Patent Examiner
January 11, 1999